II. Safety and Effectiveness Summary

A. Contact Information

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B. Device Name

Micrus MicroCoil System
Classification: Device, Artificial Embolization
Regulation Number: 882.5950
Product Code: HCG
Device Class: III

C. Predicate Device(s)

This 510k application is for a labeling change to the FDA cleared Micrus MicroCoil Systems listed in the table below:

Number	Description	Clearance Date
K002056	Micrus MicroCoil Delivery System	01/11/2001
K022420	Micrus Stretch Resistant MicroCoil System	10/22/2002

D. Device Description: Unchanged from predicates listed above.

Micrus MicroCoil Systems are platinum embolic coils ("MicroCoils") attached to Device Positioning Units (DPUs (single use, sterile). The Micrus MicroCoil Systems are available in a 10-System size (compatible with 10 and 14 sized microcatheters) and 18-System size (compatible with 14 and 18 sized microcatheters). Both 10 and 18 sizes are available in various diameters/dimensions. Shapes can be spherical, helical, or straight. Lengths range from 1 to 30 centimeters and diameters range from 2 to 20 millimeters. Implant material for the non stretch resistant MicroCoils is a platinum alloy; implant material for the stretch resistant MicroCoils is a platinum alloy and a stretch resistant member (non-absorbable polypropylene suture).

A MicroCoil is detached from its Device Positioning Unit through heat shearing of a highly oriented, high tensile strength polyethylene (PE) fiber upon the clinician's command. The Device Positioning Unit is then removed from the microcatheter and discarded.

A Micrus MicroCoil System connects to a Micrus Connecting Cable (single use, sterile) which traverses the sterile field to connect to a Micrus Detachment Control Box (DCB) (reusable, non-sterile). The Connecting Cable and Detachment Control Box are sold separately. A Micrus MicroCoil System plus Connecting Cable and Detachment Control Box is referred to as a Micrus MicroCoil Delivery System.

E. Intended Use (Indication for Use Statement)

Micrus MicroCoil Systems are intended for endovascular embolization of intracranial aneurysms.

F. Technological Comparison

There is no change in the technology from that of 510k numbers K002056 and K022420. The Micrus MicroCoil System remains the same. The only change is the Indication for Use (to be justified in the Section I, "Justification for Labeling Change Based Upon Clinical Outcomes of ISAT"

MicroCoil System (Unchanged)		
Characteristic	*Micrus MicroCoil System Predicate*	*Current Application*
MicroCoil System supplied as:	Sterile, single use. MicroCoil attached to DPU. Polyethylene introducer over coil. In plastic package hoop.	Same as predicate Same as predicate Same as predicate Same as predicate

Implantable Embolic Coil (Unchanged)		
Characteristic	*Micrus MicroCoil System Predicate*	*Current Application*
Materials of Construction	Platinum/Tungsten alloy wire & Au/Sn solder	Same as predicate
Shape	Spherical, helical, & straight	Same as predicate
Dimensions	Various diameters & lengths to treat a variety of aneurysm sizes	Same as predicate
Radiopacity	Radiopaque from Pt alloy wire	Same as predicate
MRI Compatibility	Yes	Same as predicate
Method of Attachment to Device Positioning Unit	High tensile strength, highly oriented polyethylene fiber	Same as predicate
Method of Detachment from Device Positioning Unit	Shear polyethylene fiber with a loop of resistively heated coil	Same as predicate
Provided:	Sterile, single use	Same as predicate

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Device Positioning Unit (Unchanged)		
Characteristic	*Micrus MicroCoil System Predicate*	*Current Application*
Physical	Variable stiffness. Composite introducer. Most flexible distally, medium flexibility in mid-section and stiffest proximally to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Same as predicate
Construction	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Same as predicate
Working Length	175 cm	Same as predicate
Package Configuration	In plastic packaging hoop. Introducer in place (for introduction of MicroCoil into the microcatheter).	Same as predicate
Compatible with:	Microcatheters with minimum 0.14" i.d. ("10" sized systems), or 0.16" i.d. ("18" sized systems). 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14).	Same as predicate

Connecting Cable (Unchanged)		
Characteristic	*Micrus MicroCoil Delivery System Predicate*	*Current Application*
How supplied:	Sterile, single use	Same as predicate
Physical	Single cable with proprietary connectors to fit only the Micrus Detachment Control Box and the Micrus MicroCoil System	Same as predicate
Length	262 cm.	Same as predicate

Detachment Control Box (Unchanged)		
Characteristic	*Micrus MicroCoil Delivery System Predicate*	*Current Application*
How supplied	Non-Sterile, reusable. Used outside the sterile field.	Same as predicate
Power Source	Alkaline batteries.	Same as predicate
Displays	Voltage, Current, Low Battery, Fault, Detach Cycle	Same as predicate
Detachment Cycle Duration	5 seconds	Same as predicate
Output Voltage	6.5 VDC	Same as predicate
Output Current	125 mA nominal, 200 mA max.	Same as predicate
"Detach" feedback	"Detach Cycle" light goes from illuminated to off. Also, a beep sounds once a second for 5 seconds to provide an audible countdown of the 5 second detachment time. Clinician verifies detachment fluoroscopically per device labeling.	Same as predicate
Method to attach Connecting Cable to Detachment Box	Proprietary connector; fits only one-way to assure proper polarity.	Same as predicate
Flow of Current	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	Same as predicate

Accessories (Unchanged)		
Characteristic	*Micrus MicroCoil System Predicate*	*Current Application*
Accessory Products Required to Perform the Procedure. * - Not provided as part of the system, chosen based upon physician experience and preference.	Micrus Sterile Connecting Cable	Same as predicate
	Micrus Detachment Control Box	Same as predicate
	5-7F Guide Catheter*	Same as predicate
	Microcatheter (see above)*	Same as predicate
	Guide wire compatible with microcatheter*	Same as predicate
	Continuous saline/heparin saline flush*	Same as predicate
	Rotating haemostatic valves*	Same as predicate
	3-Way stopcock*	Same as predicate
	1-Way valve*	Same as predicate
	IV pole*	Same as predicate
	Femoral Sheath*	Same as predicate
	Alkaline Batteries*	Same as predicate

This technological comparison demonstrates the Micrus MicroCoil Delivery System remains equivalent to 510k numbers K002056 and K022420

G. *Discussion of Non Clinical Tests and Conclusions (Unchanged)*

The non-clinical tests performed on the Micrus MicroCoil System were reviewed in 510k numbers K002056 and K022420. A summary of non-clinical tests and results are supplied here as a reference.

Test	*Results (Unchanged)*	*Substantial Equivalence*
Aneurysm Packing / Detachment Reliability	Characteristic: ▪ Complete occlusion of aneurysms. ▪ Detachment Reliability. Test data: ▪ No filling defects evident on angio. ▪ No premature detachment / auto-detach caused by exposure to blood, body fluids, body temperatures or repeated manipulation. 100% first detach-cycle detachment achieved.	Equivalent

Coil Stability Aneurysm Occlusion	Characteristic: Positional stability and aneurysm occlusion. Test data: Positional stability and aneurysm occlusion maintained through 6 months of implant. No coil compaction present at 6-month angio.	Equivalent
GDC Bench Marking	Characteristic: Established specifications for delivery force, tensile strength, and stiffness. The Micrus Stretch Resistant MicroCoil must be substantially equivalent to predicates. Test data: Showed substantial equivalence in delivery force, tensile, and stiffness.	Equivalent
Coil Stiffness/Softness	Characteristic: Stiffness limit desired for Finishing Stretch Resistant MicroCoil. Test data: Finishing Stretch Resistant MicroCoil and Helical Stretch Resistant MicroCoil stiffness is within desired stiffness limit.	Equivalent
Friction in the Microcatheter (Delivery Force)	Characteristic: Average push force must be substantially equivalent to predicates. Test data: Finishing Stretch Resistant MicroCoil and Helical Stretch Resistant MicroCoil average push force exhibit comparable delivery forces.	Equivalent
MDR Database Review	Characteristic: MDR review for clinical risks. Test data: MSR01 risk assessment includes and addresses all risks encountered in review of predicate device MDR review.	Equivalent
Biocompatibility of Materials	Characteristics: Meets the requirements of ISO 10993. Test data: The only new material in the Micrus Stretch Resistant	Equivalent

	MicroCoil is polypropylene monofilament # 6523. It is identical to the pre-approved GDC stretch resistant suture.	
Sterilization Validation	Characteristic: Minimum Sterility Assurance Level of 10^{-6}. Test data: Passed minimum sterility assurance level of 10^{-6}.	Equivalent
Shelf Life Test	Characteristic: No performance degradation after 1 year of shelf life aging. Test data: Minimum tensile strength after 1 year accelerated aging shows no degradation.	Equivalent
Tensile Strength	Characteristic: Tensile strength of suture ball tip and MicroCoil to DPU must be substantially equivalent to predicates. Test data: Tensile strength meets desired strength criteria.	Equivalent
Durability (Reliability after Fatigue)	Characteristic: Withstand deployment and retraction 6 times in a tortuous anatomy. Test data: No knotting, no breakage, no stretching occurred. Durability meets desired durability criteria.	Equivalent
MRI Compatibility of Implant	No change was made which would impact MRI compatibility.	Equivalent

H. Justification for Labeling Change of "Indication for Use" Statement

Background

Endovascular coiling of intracranial aneurysms has been in clinical practice in Europe since 1992 and since 1995 in the U.S. Prior to the advent of safe, detachable coil systems, patients with intracranial aneurysms had only one option: craniotomy and clipping. In the past 10 years, coiling has gained acceptance world wide as a viable option to surgical clipping.

Initially, endovascular coiling was viewed as an alternative to be used only when surgery was ill advised due to an aneurysm's shape or location, or to a patient's poor condition. Therefore, initially it was appropriate to label coils as intended for use in cases where the surgery was deemed to be high risk or impossible.

Over the past 10 years many improvements have been made in endovascular techniques making coiling a superior option to surgery, as demonstrated in a recent multi-center study published in the Lancet. The purpose of the study was to compare outcomes of endovascular coiling to surgical clipping. Based upon the results of this study, in which Micrus MicroCoils were used (along with GDC and Cook coils) Micrus Corporation is requesting a change to its "Indication for Use" statement.

Micrus Corporation received CE Marking for the Micrus MicroCoil System in May 2000, followed by FDA market clearance in January 2001. After regulatory clearance, Micrus applied to the International Subarachnoid Aneurysm Trial Steering Committee for inclusion in their multi-center study. Permission was granted in February 2001. Micrus MicroCoils continued to be used in the study until study enrollment ended in June 2002.

Brief Overview of the International Subarachnoid Aneurysm Trial (ISAT)

Reason for the Study

ISAT was designed to establish the relative benefits of endovascular coiling versus surgical clipping for intracranial aneurysms in patients with ruptured intracranial aneurysms.

Methods

- ISAT enrolled 2143 patients with ruptured intracranial aneurysms and randomly assigned them to neurosurgical clipping (n = 1070) or endovascular treatment with platinum coils (n = 1073).
- Clinical outcomes were assessed at 2 months and at 1 year.
- The primary outcome was a neurological assessment of dependency at 1 year (using the Rankin neurological outcome scale).

Findings

- 23.7% of endovascular patients were dependant or dead at 1 year.
- 30.6% of surgical patients were dependant or dead at 1 year.
- The relative risk reduction for endovascular patients (versus surgical) was 22.6%.
- The absolute risk reduction for endovascular patients (versus surgical) was 6.9%.
- The risk of rebleeding at 1 year for the endovascular patients was 2 per 1276.
- The risk of rebleeding at 1 year for the surgical patients was 0 per 1081.

Interpretation

- The outcome in terms of survival, free of disability at 1 year, is significantly better with endovascular coiling.
- Long-term risks of further bleeding are low from either therapy, although slightly more frequent with endovascular coiling.

Proposed Labeling Change to "Instruction for Use" pamphlet

Based upon the results of ISAT, Micrus Corporation proposes changing the current "Indication for Use" statement.

- The proposed "Indication for Use" labeling is as follows:

  The ACT Platinum MicroCoil Systems are intended for endovascular embolization of intracranial aneurysms.

K031578

I. *Summary of Safety and Effectiveness*

Based upon the clinical trail results cited in the Lancet, it is concluded that the Micrus MicroCoil System (one of 3 platinum embolic coil systems used in this scientifically rigorous randomized trial) demonstrated treatment outcome is significantly better with endovascular coiling than with surgical clipping.

Margaret Webber
Director, Regulatory & Clinical Affairs
Micrus Corporation
May 07, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Ms. Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
610 Palomar Avenue
Sunnyvale, California 94085

Re: K031578
Trade/Device Name: Micrus MicroCoil Systems
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: May 7, 2003
Received: June 3, 2003

Dear Ms. Webber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: **Micrus MicroCoil Systems** 510(k) Number (if known):

Indications for Use:

Micrus MicroCoil Systems are intended for endovascular embolization of intracranial aneurysms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: ✓
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031578